

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)


REC'D 28 SEP 2004

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| Applicant's or agent's file reference<br>12234320   | <b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). |  |
| International Application No.<br><br><b>PCT/AU2003/000717</b>   | International Filing Date<br><i>(day/month/year)</i><br>6 June 2003  | Priority Date <i>(day/month/year)</i><br>7 June 2002 |
| International Patent Classification (IPC) or national classification and IPC<br>Int. Cl. <sup>7</sup> C07D 235/26, 235/28, 307/83, A61K 31/4184, 31/585 |  |  |
| Applicant<br>CORTICAL PTY LTD et al   |  |  |

|    |  |
|----|--|
| 1. | This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.   |
| 2. | This REPORT consists of a total of 6 sheets, including this cover sheet.<br><br><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).<br><br>These annexes consist of a total of      sheet(s).   |
| 3. | This report contains indications relating to the following items: <ul style="list-style-type: none"> <li>I    <input checked="" type="checkbox"/> Basis of the report</li> <li>II   <input type="checkbox"/> Priority</li> <li>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li>IV   <input type="checkbox"/> Lack of unity of invention</li> <li>V    <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI   <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input checked="" type="checkbox"/> Certain observations on the international application</li> </ul> |

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|---|---|
| Date of submission of the demand<br>7 January 2004  | Date of completion of the report<br>17 September 2004   |
| Name and mailing address of the IPEA/AU<br>AUSTRALIAN PATENT OFFICE<br>PO BOX 200, WODEN ACT 2606, AUSTRALIA<br>E-mail address: pct@ipaaustralia.gov.au<br>Facsimile No. (02) 6285 3929 | Authorized Officer<br><br><b>IAN DOWD</b><br>Telephone No. (02) 6283 2273 |

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,  
pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of
- ☐ the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 1-35 (in part)

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. original 1-35 (in part)

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

|                               |                              |     |
|-------------------------------|------------------------------|-----|
| Novelty (N)                   | Claims 1-30 (in part), 35-38 | YES |
|                               | Claims 31-34                 | NO  |
| Inventive step (IS)           | Claims 1-30 (in part), 35-38 | YES |
|                               | Claims 31-34                 | NO  |
| Industrial applicability (IA) | Claims 1-38                  | YES |
|                               | Claims                       | NO  |

**2. Citations and explanations (Rule 70.7)**

This preliminary examination is based on the documents cited in the International Search Report, as follows:

D1: WO 2001 077083 A1 (page 24 Example 1, and page 6 compound (XII))

D2: WO 2001 092239 A1 (See examples)

D3: WO 2001 044223 A1 (See examples, claims)

D4: WO 1999 036402 A1 (See page 12, compound IV, page 13 compound IX, and fourth compound on page 13.)

D5: WO 1996 010026 A1 (See page 6, compound (I-d))

D6: EP 0462831 A2 (See page 12, line 38; page 13 lines 35 and 51)

D7: FR 2688504 A1 (See compounds of formula (I) and (IV))

D8: US 4400319 (See columns 6 and 7, Table 1)

D9: DD 292452 A5 (See compounds of formula (I) and examples)

D10: US 4329477 (See whole document)

D11: US 3775333 (See Example 1)

D12: GB 876015 (See first page, right-hand column, lines 69-74)

D13: US 2933503 (See examples)

D14: US 2843597 (See whole document)

D15: STN File HCA, Abstract 115:256067

Continued on supplemental sheet

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1-35 are not fully supported by the description and are an unreasonable extrapolation of the work the applicant has actually done. The claims define a broad number and variety of benzo-fused heterocyclic compounds, yet in the description there is only support for the benzimidazolin-2-ones disclosed in the examples. While the applicant is not required to exemplify every embodiment of the invention, there should at least be some uniform spread of examples throughout the claimed group - currently there are whole classes of compounds defined in the claims that are unrepresented in the examples. Without ample descriptive support, or without more narrow and precise definitions of the compounds of formula (I), the claims are regarded as an unreasonable extrapolation of the work the applicant has actually done.

**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Sheet V Box 2**

D16: STN File HCA, Abstract 52:77210

D17: STN File HCA, Abstract 52:72309

Claims 31-34 are not novel or inventive when compared to D1-D17 which disclose compounds, at the relevant passages mentioned above, which fall under the scope of the claims.

Claims 1-30 are novel and inventive in regard to the matter that has been searched (i.e. the benzimidazolin-2-ones disclosed in the examples), because none of D1-D17 disclose a method of inhibiting cytokine or biological activity of MIF using the compounds of formula (I) or immediately suggest that the compounds could be used in that particular method.

Claims 35-38 are novel because none of D1-D17 disclose compounds falling under the scope of these claims.

Claims 1-38 meet the requirements of industrial applicability.